

**Models,  
Metadata,  
and  
Messaging:**

**Exploring Standards  
Governance in the CDISC Era**

High performance. Delivered.

Ken Stoltzfus

October 13, 2014

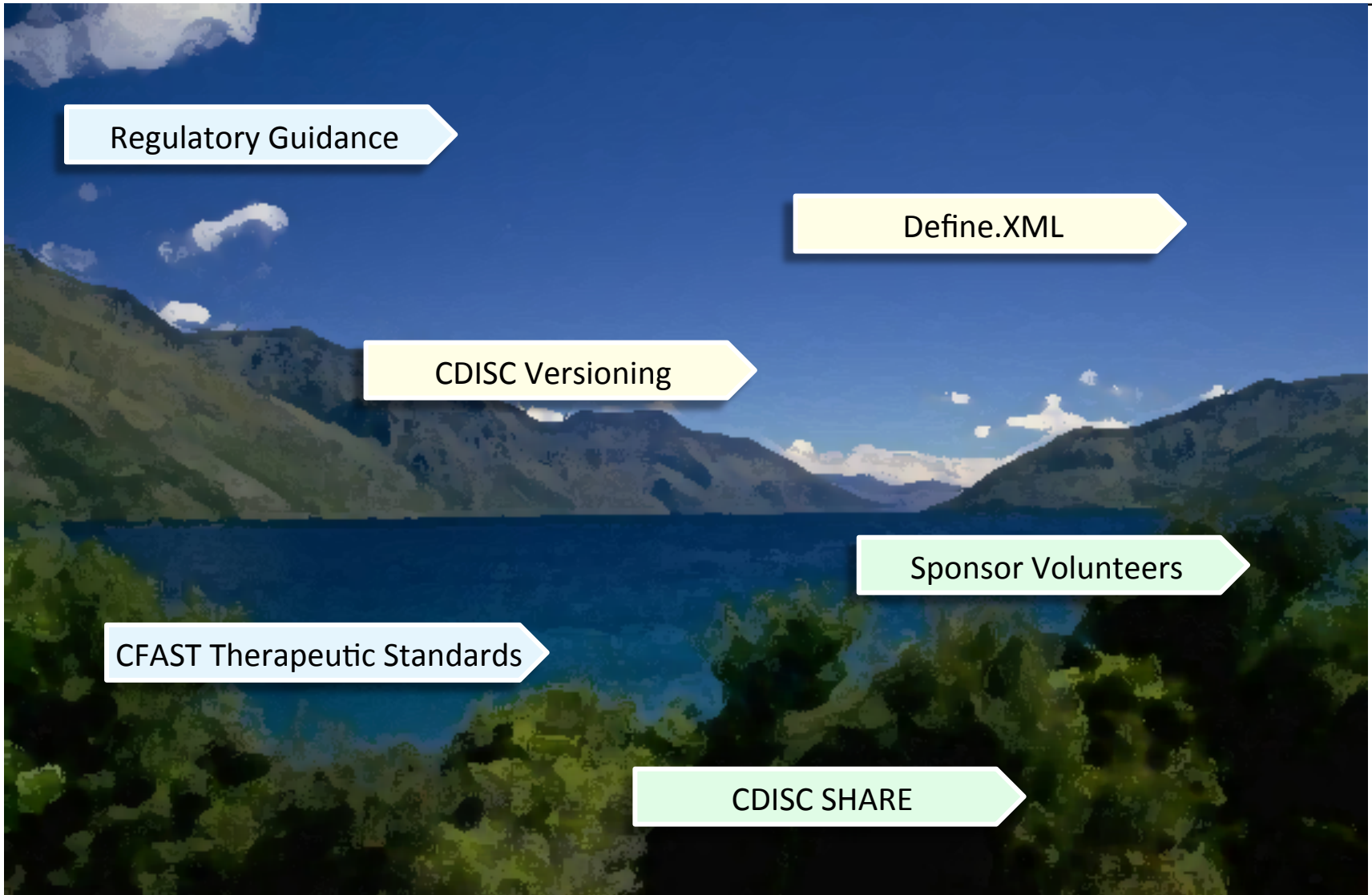
# Agenda

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**CDISC Landscape**

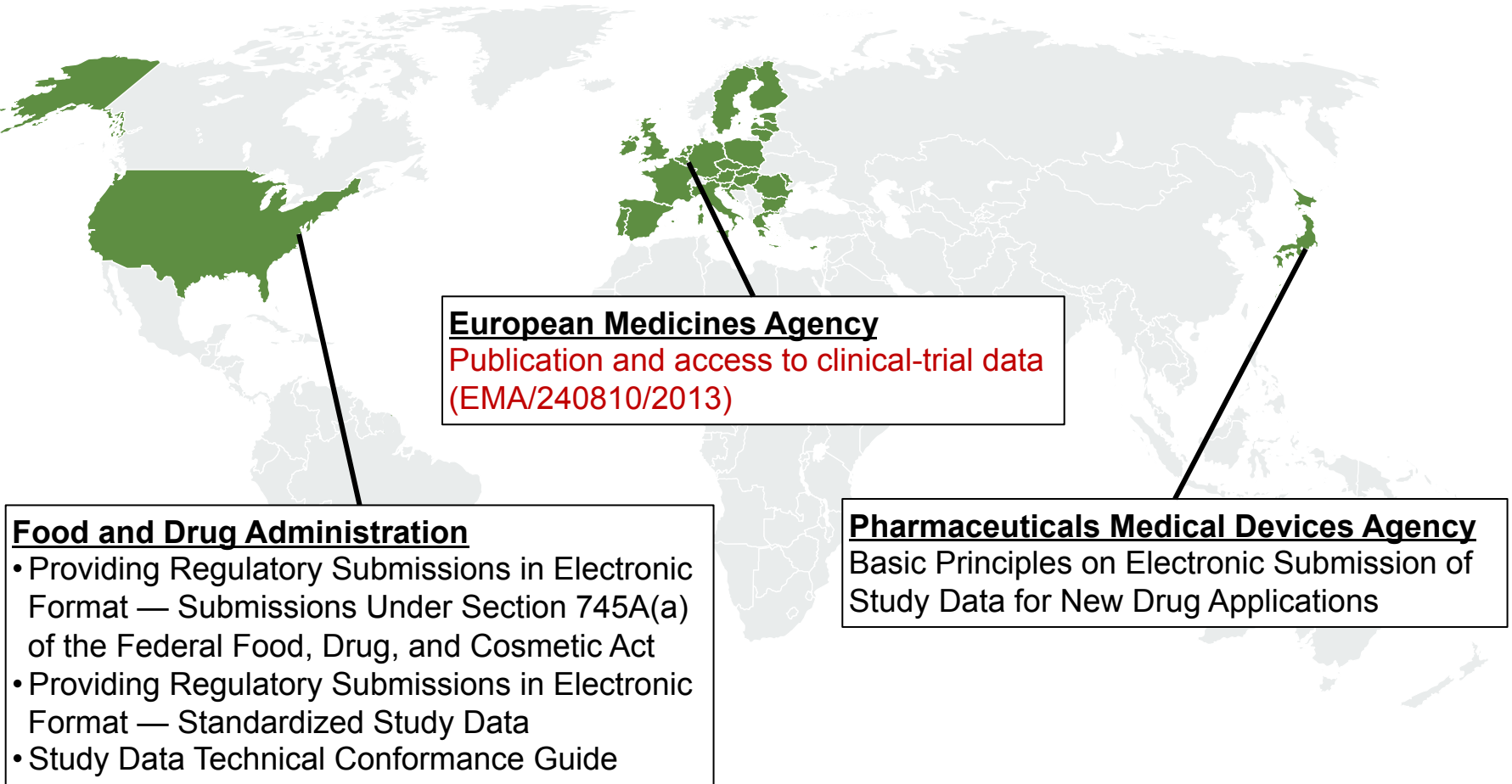
**Case Studies of Standards  
Governance**

# The CDISC Landscape in the Industry



# Impending Regulatory Requirements for CDISC

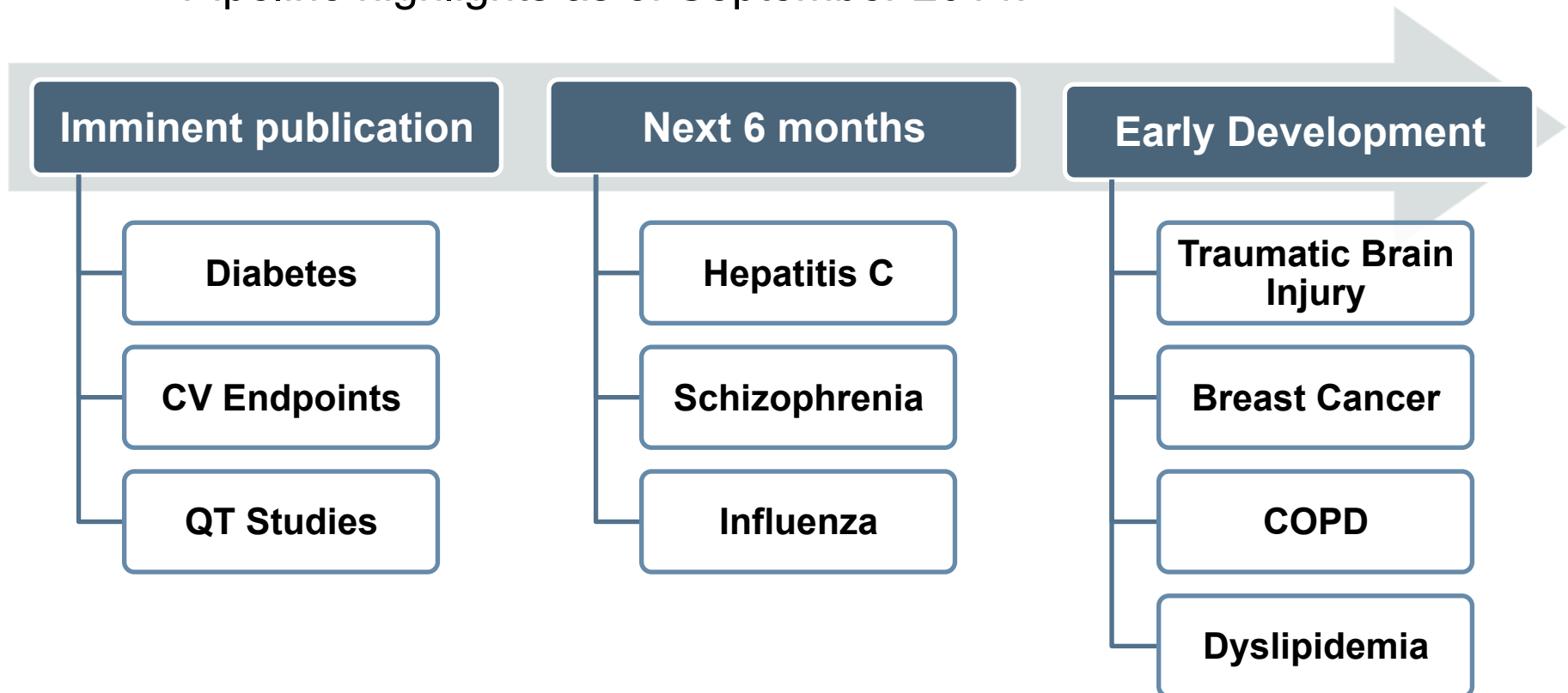
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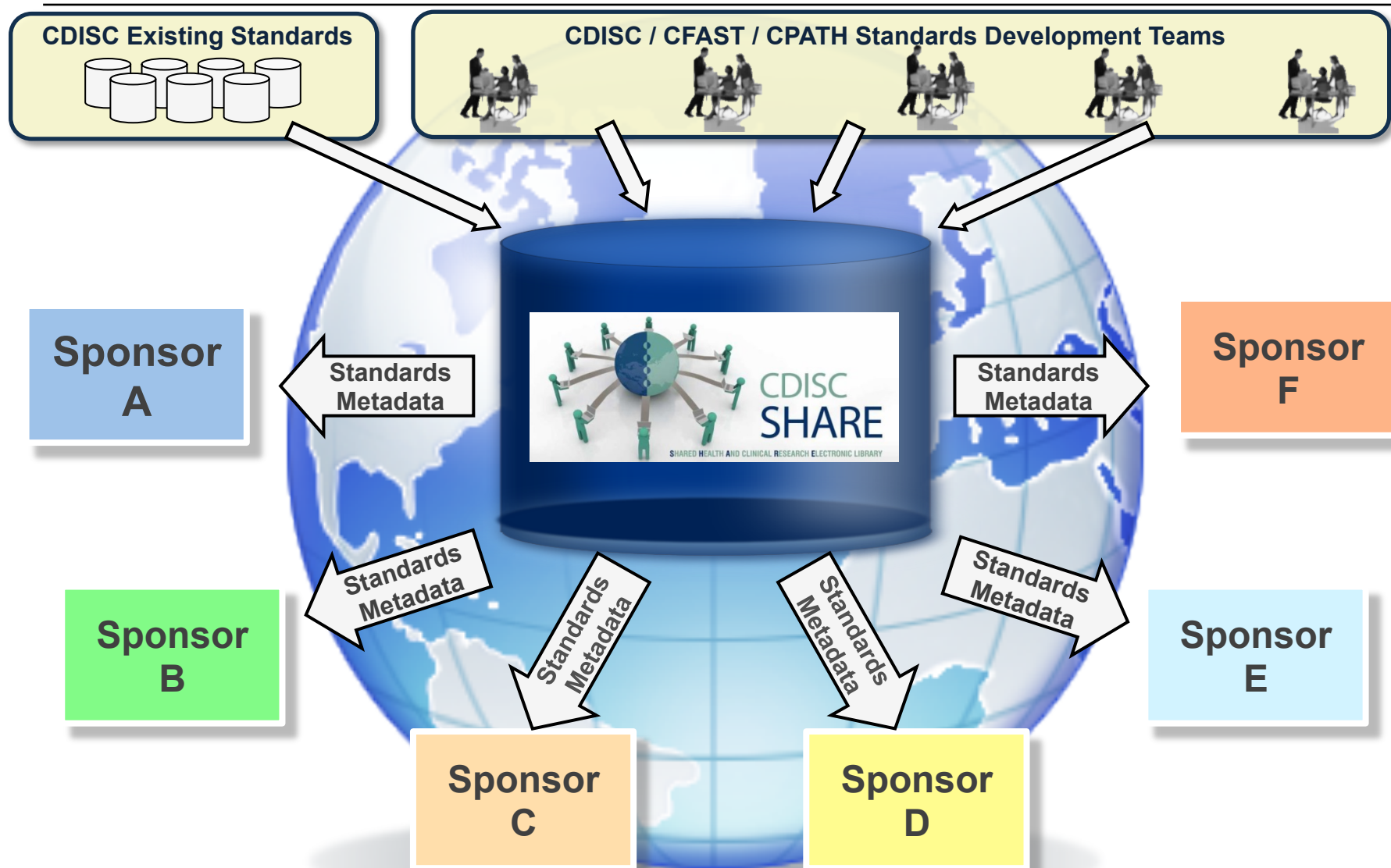
# CFAST Therapeutic Area Standards

## Coalition For Accelerating Standards and Therapies

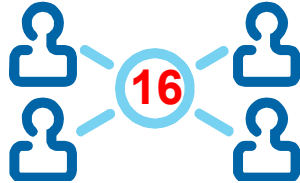
- Formed in 2012
- Well-structured development process
- Pipeline highlights as of September 2014:



# CDISC SHARE in the Industry



# Case Studies - Process



## Background:

- Mixture of full-time and part-time resources in standards governance
- Integrating 2 very different legacy corporate cultures
- Standards activities always on the critical path

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## Standards Governance:

- New standards development processes were not correctly sequenced among existing trial execution processes
- Development of standards was singularly tied to FPI date
- Use of unstable draft protocol as origin of standards requests
- Partially developed standards were released for use (and considered “at risk”)

# Case Studies - Process



## Background:

- Mixture of full-time and part-time resources in standards governance
- Needed to standardize in order to gain efficiencies from outsourcing partners
- Directive to use standards from VP-level leadership

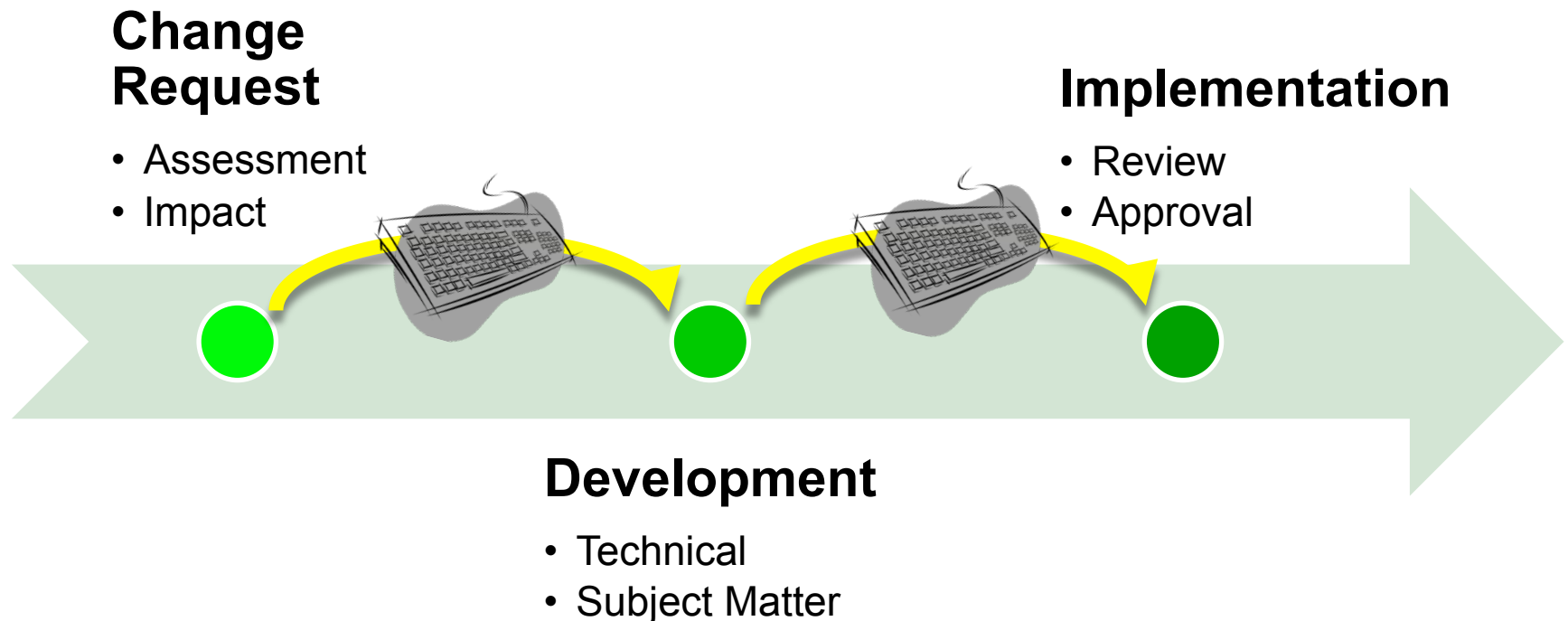
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## Standards Governance:

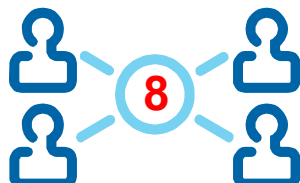
- Standardized, accessible electronic request structure that effectively logged and tracked the requests and the decision-making
- Governance processes within MDR as system-controlled workflows
- Protocol must be finalized before standards development efforts begin
- Standards development independent of the study timelines that generated the request (escalation process existed)
- Transparent prioritization of requests based on “top-priority” compounds

# Governance Workflows

- Technical measures in the MDR that ensure that the metadata is created and maintained via standard processes according to standard requirements



# Case Studies - Leveraging Metadata



## Background:

- Only part-time resources in standards governance
- Hurried, beleaguered initiative to generate metadata for use in a forthcoming MDR
- Buy-in for standards from only 1 functional area

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## Standards Governance:

- Collection of cross-functional experts informally assembled to approving standards requests (with no credible leader)
- Inordinate percentage of approval time spent debating eCRF format
- All metadata in massive spreadsheet that spanned collection, analysis, and submission data
- Compilation of metadata was difficult to acquire across multiple groups with conflicting priorities and agendas

# Case Studies - Leveraging Metadata



## Background:

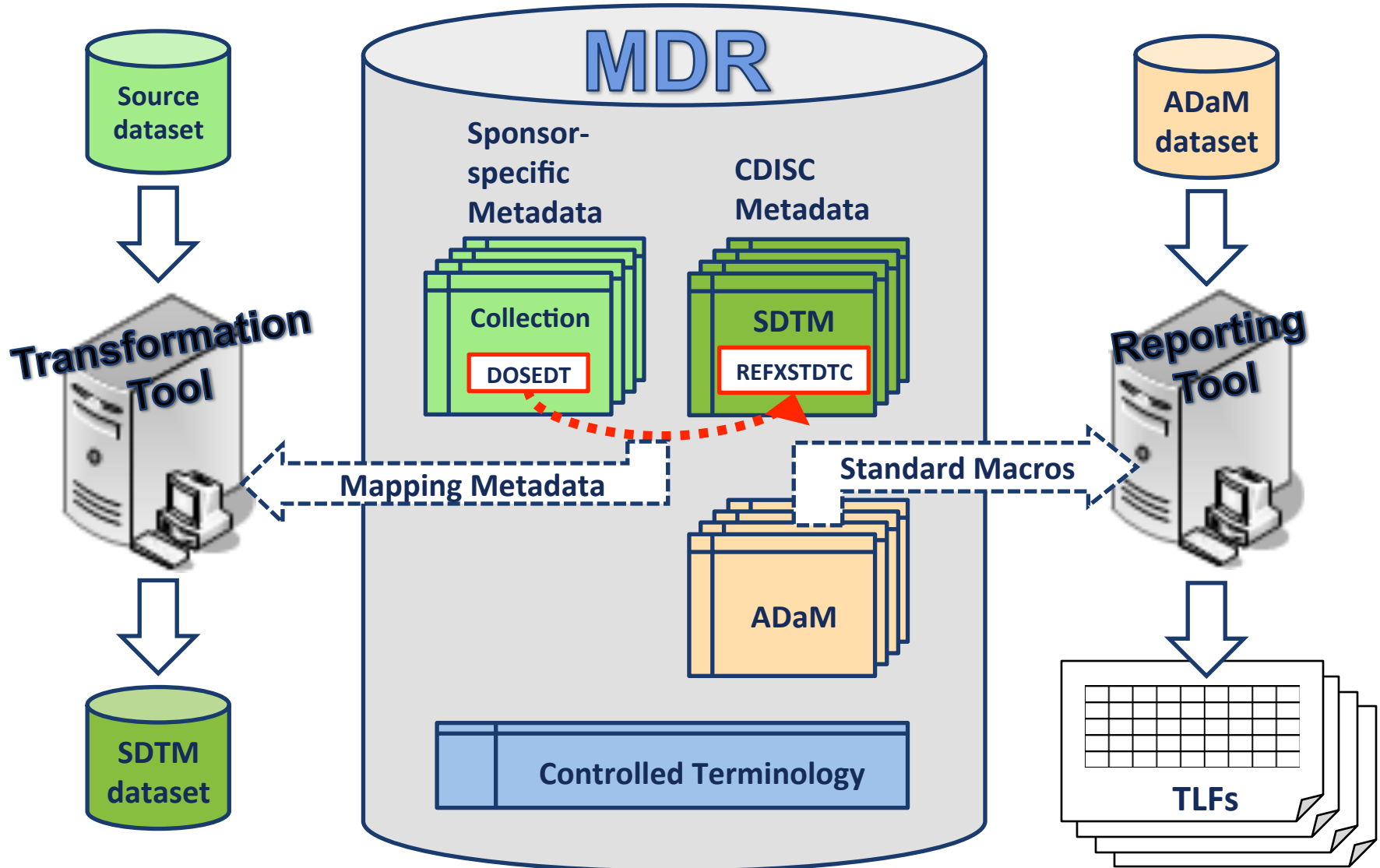
- Only part-time resources in standards governance
- Adopted CDASH and SDTM to standardize in order to effectively address regulatory questions
- Wanted to generate metadata for use in a new MDR

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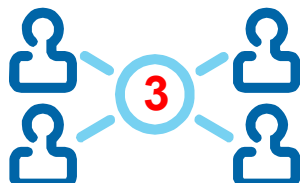
## Standards Governance:

- Broad cross-functional input into implementation of CDASH & SDTM, despite little standards governance
- The driving factor for the initiative was to ensure maximum utilization of the investment in MDR
- Leverage standard SDTM mappings within MDR to execute transformations from collection to SDTM
- Leverage standard macros within MDR to execute analysis programs

# Leveraging Metadata in the Real World



# Case Studies – Messaging and Compliance



## Background:

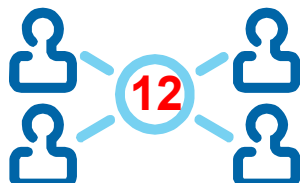
- Only part-time resources in standards governance
- Multiple business units, autonomous in both trial execution and budget
- Prevalent corporate culture of empowerment / flexibility

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## Standards Governance:

- Few small pockets of standards governance in CRF Design attempting to introduce consistency and CDISC concepts
- No high-level messaging on benefits or usage of standards
- Difficult for Drug Safety group to efficiently manage safety data from multiple clinical sources
- Currently at risk when regulatory authorities ask for SDTM or ADaM in submissions

# Case Studies – Messaging and Compliance



## Background:

- Mixture of full-time and part-time resources in standards governance
- Needed to fully standardize in order to gain efficiencies from outsourced partners
- Standards initiative emerged out of data management

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## Standards Governance:

- Highly visible VP issued messaging requiring the usage of standards
- Initial standards governance for standard collection modules only
- Compliance of collection modules achieved through a pro-active, library-based process for eCRF and database build
- Expansion of standards governance downstream via the use of analysis specs up-front when collection modules are approved

# Takeaways on Standards Governance

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Unique situations require unique solutions



Leverage metadata and technology



Standards without governance dissolve into no standards at all



Consider the customer



Balance of standardization and innovation

# Contact Information

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## Ken Stoltzfus

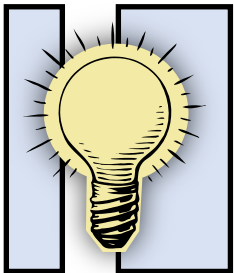
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***Feel free to visit the Accenture booth for  
more information on Accenture's solutions***

# Questions

